

ABSTRACT

The present invention relates to a novel form of cross-linked high amylose starch and processes for its manufacture. Such cross-linked high amylose starch is useful as an excipient in a controlled-release pharmaceutical formulation when compressed with pharmaceutical agent(s) in a tablet. Such cross-linked high amylose starch is prepared by (a) cross-linking and chemical modification of high amylose starch, (b) gelatinization, and (c) drying to obtain a powder of said controlled release excipient. In a preferred embodiment, such cross-linked high amylose starch is prepared in the following steps: (1) granular cross-linking and additional chemical modification (e.g., hydroxypropylation) of high-amylose starch; (2) thermal gelatinization of the starch from step (1); and (3) drying the starch from step (2) to yield a powder capable of being used as a controlled release excipient.